



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,978	07/16/2003	K. Roger Aoki	16952CON1DIV11	2159

7590 07/08/2005

Stephen Donovan
Legal Department, T2-7H
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/621,978	Applicant(s) AOKI ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 and 21-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. <u>3-16-05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The preliminary amendment filed, 7-16-03, is acknowledged. Claims 1-17 and 19-20 were canceled and claims 21-29 were added. Claims 18, 21-29 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 18, 21, 22-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,887,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US Patent claims a method of treating pain associated with muscle disorder, the method comprising the steps of administering an effective amount of botulinum toxin type B to a patient thereby reducing pain associated with muscle disorders (see claim 1 of the US Patent). Note that claim 26 recites pain associated with muscle contractions. The US

Art Unit: 1654

Patent claims the use of botulinum toxin type B for the treatment of muscle contractions similar to claims 21 and 27 of the US patent. The difference between the US patent and the instant claims is that the US Patent does not specifically claim pain as a result of arthritis and the dosage of botulinum toxin used.

However, Although the US Patent does not claim the specific dosage as in the instant application, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. Thus, one would be motivated to find the optimum dosage to treat muscle pain using botulinum toxin.

As for the arthritis, arthritis pain is a specific to pain associated with a muscle disorder. It would have been obvious to use the botulinum toxin to treat arthritic muscular pain because the US Patent claims the botulinum toxin as a general analgesic for pain associated with muscular disorders.

2. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,113,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Art Unit: 1654

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1).

Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G and the dosage amount can be between 10^{-3} U/kg to 60U/kg (see claim 2 and 3), and more specifically 1U/kg to 20U/kg (see claims 8) . The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

***Different Inventors, Common Assignee, Obvious Inventions, No Evidence of
Common Ownership at Time of Invention***

3. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,113,915. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 2).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP §

Art Unit: 1654

2302). Commonly assigned 6,113,915, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

4. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,235,289. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G (see claim 2 and 3). The difference between the US Patent and the instant application is that

Art Unit: 1654

the US Patent does not teach the treatment of pain associated arthritis and the dosage claimed.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for the dosage, although the US Patent does not claim the specific dosage as the instant application, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. Thus, one would be motivated to find the optimum dosage to treat muscle pain using botulinum toxin.

***Different Inventors, Common Assignee, Obvious Inventions, No Evidence of
Common Ownership at Time of Invention***

5. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,235,289. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 4).

Art Unit: 1654

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,235,289, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

6. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,333,037. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1).

Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G

Art Unit: 1654

and the dosage amount can be between 10^{-3} U/kg to 60U/kg (see claim 2 and 3), and more specifically 1U/kg to 20U/kg (see claims 8) . Note that this dosage ranger significantly overlaps the dosage range claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

***Different Inventors, Common Assignee, Obvious Inventions, No Evidence of
Common Ownership at Time of Invention***

7. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,333,037. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 6).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,333,037, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show

Art Unit: 1654

that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

8. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,372,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US patent claims a method for treating pain, the method comprising the step of intrathecal or intraspinal administration of an effective amount of a botulinum toxin to a mammal, thereby alleviating pain experienced by the mammal, wherein the botulinum toxin (see claim 1). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G and the dosage amount can be between -3U/kg to 60U/kg (see claim 3) . Note that this dosage ranger significantly overlaps the dosage range claimed in the instant application. The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would

Art Unit: 1654

have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

***Different Inventors, Common Assignee, Obvious Inventions, No Evidence of
Common Ownership at Time of Invention***

9. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,372,226. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 8).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,372,226, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Art Unit: 1654

10. Claims 18, 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,500,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to a method of relieving pain associated with contractions in arthritis, using botulinum toxin.

The US Patent claims a method for reducing pain in a patient, comprising subcutaneous, intramuscular or intrathecal administration of a therapeutically effective amount of an agent to the patient, wherein the agent comprises a botulinum toxin component covalently coupled to substance P (see claim 13). Similar to the instant application, the botulinum toxin can be either A, B, C, D, E, F, and G (see claim 14), and The difference between the US Patent and the instant application is that the US Patent does not teach the treatment of pain associated arthritis, the dosage claimed and the US Patent claims that botulinum toxin is complexed with substance P.

However, since the US Patent claims a method of treating pain , it would have been obvious that the injection of Botulinum toxin has some analgesic effect. As such, it would have been obvious to use botulinum toxin to treat pain, regardless of source or cause of pain. Thus the claimed invention of the US Patent and claimed invention of the instant application are not patentably distinct from each other.

As for the dosage, although the US Patent does not claim the specific dosage as the instant application, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a

Art Unit: 1654

claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. Thus, one would be motivated to find the optimum dosage to treat muscle pain using botulinum toxin.

Finally, the instant claims recite the administration of botulinum toxin. The instant claims do not exclude complexes that comprise botulinum toxin. Since the US patent claims botulinum toxin as an agent for the treatment of pain, the instant claimed limitations are met. Accordingly, the US Patent and claimed invention of the instant application are not patentably distinct from each other.

***Different Inventors, Common Assignee, Obvious Inventions, No Evidence of
Common Ownership at Time of Invention***

11. Claims 18, 21-29 are directed to an invention not patentably distinct from claims 16 of commonly assigned US 6,500,436. Specifically, for the reasons set forth in the previous paragraphs (paragraph no. 10).

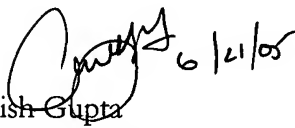
The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,500,436, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to

Art Unit: 1654

resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner